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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,444

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Eric A. Goldfarb

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,444

Applicant(s)

GOLDFARB ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/3/04, 2/2/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 11 is objected to because of an informality, which can be corrected as follows: In line 1, "element" should be replaced by --portion--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6, 16, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 6, at least one proximal and at least one distal element and said to "atraumatically capture the valve leaflets." That is, the leaflets, which are unpatentable parts of the human body, are essentially claimed to be structural parts of the invention. With respect to claims 16 and 31, it is not certain how the capture device is detachable from the interventional tool or how the capture device is detached from the interventional tool, since the interventional tool comprises the capture device. That is, how is the capture device detachable or detached from itself?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3731

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Booker (5,562,678). Booker discloses, at least in figures 5-11 and in col. 5, lines 15-26; an interventional tool, where the tool includes a capture device having a shaft (60), a proximal portion (at 45), a distal portion (at 30), at least one deployable distal element (30), and at least one deployable proximal element (45), where the at least one distal element is deployable and retractable independently of the at least one proximal element in an outward direction from the shaft, where at least one proximal element and at least one distal element has a loop shape and comprises nitinol. The introductory statement of intended use (“for repairing a cardiac valve”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Booker’s device, which is capable of being used as claimed if one desires to do so.

6. Claims 1-12, 15, 17-27, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al. (6,626,930). Allen et al. disclose, at least in figures 4a-4c and in col. 7, line 66 to col. 8, line 8; an interventional tool (80) and a method with the tool for repairing a cardiac valve, where the tool and method include a capture device having a

Art Unit: 3731

shaft (unlabeled element at the top of figures 4a-4c)), a proximal portion (at 86), a distal portion (at 84), at least one deployable distal element (84), and at least one deployable proximal element (86), where the at least one distal element is deployable and retractable independently of the at least one proximal element in an outward direction from the shaft; where the at least one distal element has an adjustable length extending from the shaft to a tip of the at least one distal element, where the at least one distal element and the at least one proximal element are deployable by respective angular movement of the at least one distal element and the at least one proximal element (i.e., angular movement with respect to the leaflets), so that at least one distal element or at least one proximal element forms an angle with the shaft (i.e. an angle between a tip of a distal element or a proximal element and the distal tip of the shaft); where the at least one proximal element and the at least distal element are configured to atraumatically capture the leaflets, where the at least one distal element and the at least one proximal element each includes a frictional accessory (88), where the at least one proximal element and the at least one distal element are adapted to be adjusted angularly (with respect to the leaflets) after capturing the leaflets, where the distal portion comprise two distal elements on opposite sides of the shaft and are simultaneously deployable (see fig. 4a), where the proximal portion comprises two proximal elements on opposite sides of the shaft and are simultaneously deployable (see fig. 4a), where at least one distal element and at least one proximal element are adapted to fixedly hold the leaflets as captured (see figs. 4b and 4c), and where the at least one proximal element is configured to be disposed within the edges of the corresponding at least one distal

element when both the at least one proximal element and the at least one distal element are in a deployed position (i.e. the edges as viewed along the longitudinal axis of the shaft from the distal end of a distal element).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. Allen et al. disclose the invention substantially as claimed, but do not disclose the method substantially as claimed, but do not disclose repositioning the capture device in relation to the leaflets and redeploying the at least one distal element and the at least one proximal element so that the valve leaflets are captured therebetween and that the cardiac valve is evaluated for regurgitation. Nevertheless, Allen et al. teach in col. 3, lines 4-13, col. 7, lines 9, and col. 8, lines 3-8; that surgical procedures with the interventional device are conducted under various means of

imaging, and that the proximal and distal elements are individually actuated in order to grasp the leaflets. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reposition the capture device in relation to the leaflets and redeploy the at least one distal element and the at least one proximal element in order to individually grasp the valve leaflets (which are in variable positions) and stabilize them at desired positions with respect to each other; and it would be obvious to evaluate (i.e., visualize or image) the cardiac valve for regurgitation during a surgical procedure in order to observe the effects of valve-leaflet stabilization.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Coddington, III et al. (5,190,554), Seguin (6,461,366), and Abe (6,966,914) teach interventional tools including capture devices.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

November 19, 2006